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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,277	04/05/2006	Radka Milanova	7865-206 MIS:jb	2819

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09/29/2008

EXAMINER

TSAY, MARSHA M

ART UNIT	PAPER NUMBER
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1656

MAIL DATE	DELIVERY MODE
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09/29/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/517,277	Applicant(s) MILANOVA ET AL.	
	Examiner Marsha M. Tsay	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46, 48, 49 and 51-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-46, 48, 49 and 51-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>06.20.08; 08.05.08</u> . | 6) <input type="checkbox"/> Other: _____ |

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This Office action is in response to Applicants' remarks received June 20, 2008.

Applicants' arguments have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous Office actions are hereby withdrawn.

Claims 47, 50 are canceled. Claims 1-46, 48-49, 51-53 are currently under examination.

Priority: The request for priority to provisional application 60/401782, filed August 8, 2002, and provisional application 60/390126, filed June 21, 2002, is acknowledged.

Objections and Rejections

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 49 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 49 recites said solvent removal step is effected by air-desolventizing at a temperature of about 15°C to about 25°C. However claim 1 already recites desolventizing under vacuum. Therefore, claim 49 does not make sense.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 5-10, 17-19, 29-31, 35, 44-48 remain rejected under 35 U.S.C. 103(a) as being obvious over Murray (US 6005076; IDS; previously cited) in view of Rossi et al. (Lebensmittel-Wissenschaft Und-Technologie 1982 Istituto Di Technologie Alimentari, Univ. Degli Studi Di Milano, Via Celoria 2, 20133, Milan Italy 15(5): 309-312; IDS 07.25.06; previously cited).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

In Example 3 (col. 7, lines 60-67), Murray discloses a process of initially preparing a protein isolate using a meal prepared from the cold pressing of canola seeds to give a consistency similar to canola meal, followed by a protein extraction and recovery process (as described in

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Example 2). According to Murray, the “canola meal” may be any canola meal resulting from the removal of canola oil from canola seed (col. 2-3, lines 66-2). In Example 2, Murray discloses that meal from rapeseed containing 32.5% protein, 10.1% fat and 6.1% moisture was extracted with an aqueous salt solution and agitation (col. 7 lines 37-40). It would be reasonable for one of ordinary skill to recognize that the initial rapeseed meal having a moisture content of 6.1% would be essentially a dried meal product that is desolventized. The aqueous meal/salt solution was mixed for 2 hours at 25°C to remove residual meal and then chilled to 8°C followed by centrifugation (col. 7 lines 5, 40-43). Murray discloses the aqueous salt solution with an ionic strength value of less than 0.8 and within the range of 0.3 to 0.6 (col. 8, lines 62-63), a pH range of 5.3 to 6.2 (col. 8, line 66-67), and wherein the aqueous protein solution has a concentration of about 10-100 g/L of protein (col. 9, lines 1-3). In addition, Murray discloses that the formation of protein isolates into micelles is achieved optimally at pH values of 5.3 to 6.2 (col. 3, lines 46-50). After separating the aqueous protein solution from the residual oil seed meal, Murray discloses a process step for increasing the protein concentration using a selective membrane technique, diluting the concentrated protein solution by 15 fold at 6° C to form protein micelles, settling the protein micelles, and recovering the protein mass to provide a dried proteinaceous powder having a protein content of at least 90 wt % (col. 7, lines 12-30, col. 8, lines 31-61). Murray does not explicitly teach a desolventized oil seed meal under vacuum (i.e., the steps of 1(b) and 1(c)).

Rossi et al. disclose that to obtain a protein meal, an initial oil-extraction process is used to obtain a "cake" that is rich in protein. Rossi et al. further disclose a desolventizing under

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vacuum technology can be performed at 40°C of said cake to obtain a protein meal (p. 309, 310 Figure 1, p. 311 column 2).

The instant claims are essentially drawn to a process of preparing a protein isolate comprising processing a desolventized oil seed meal. The desolventized oil seed meal is obtained by the process described in claims 1(a)-1(c). The actual process to recover protein isolate from the desolventized oil seed meal is described in claims 1(d)-1(i).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Murray of obtaining a protein isolate by first crushing canola seeds (claim 1a), substituting the oil-extraction process (claim 1b) and desolventizing under vacuum process (claim 1c) of Rossi et al. to obtain a desolventized oil seed meal and then processing said desolventized oil seed meal to obtain a protein isolate by extracting said desolventized oil seed meal to cause solubilization and to form an aqueous protein solution having a pH of about 5-6.8, maintain the aqueous solution at an ionic strength and pH range that is suitable for the formation of protein micelles (claim 1, 2, 5-10, 17-19), increase the protein concentration (claim 1), dilute the concentrated protein solution to induce the formation of protein micelles (claim 1, 2, 29-31), settle the protein micelles, and recover the protein micelles to make a dry proteinaceous powder having a protein content of at least 90 wt % (claim 1, 35) because Murray provides and suggests motivation for a method of preparing a protein isolate from a desolventized oil seed meal and Rossi et al. teach a desolventized oil seed meal under vacuum.

Though, Murray provides working examples using canola meal, the process may be used for other oil seed meals, such as soybean meal and rapeseed meal (col. 2, lines 60-62), as well as

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proteinaceous material, such as proteins from naturally occurring oil seeds or proteins obtained by genetic manipulation (col. 2, lines 62-65). In col. 3, Murray also discloses that the canola meal may be any canola meal resulting from canola seed with varying levels of non-denatured protein, from hot hexane extraction or cold oil extrusion methods (col. 3, lines 1-5).

It would have been obvious to a person having ordinary skill in the art to prepare a protein isolate with any appropriate oil seed meal (claim 1, 44-48) because Murray provides and suggests motivation for using a proteinaceous material to prepare a protein isolate having a protein content of at least 90 wt % (col. 8 lines 31-61).

As previously noted in Applicants remarks received December 17, 2007, the instant application is directed to a process of preparing a protein isolate by a plurality of steps starting with oil seeds. The oil seeds are crushed to form oil and oil seed meal therefrom. The oil seed meal is solvent extracted to recover residual oil therefrom and then the solvent is removed from the extracted oil seed meal at a temperature below 50°C to provide a desolventized oil seed meal. It is this desolventized oil seed meal which is processed to recover the protein isolate (p. 12 of remarks). It is conceded that the Murray et al reference describes steps (d) to (i) of claim 1. It is submitted that the Murray reference does not disclose or suggest the combination of steps with steps (a) to (c) of claim 1 with steps (d) to (i).

Applicants have also currently amended claim 1(c) to include the limitation that the desolventized oil seed meal is obtained under vacuum.

Applicant's arguments have been fully considered but they are not persuasive.

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As noted above, the Murray reference discloses the steps of 1(a), 1(d) to 1(i). Murray further disclose that the material to be solubilized (beginning at step 1d) is an oil seed meal (i.e. canola meal) (col. 2 lines 58-60). The canola meal is any type of canola meal resulting from the removal of canola oil from canola seed from an appropriate method (col. 3 lines 1-5). In their working examples, Murray discloses canola seeds were initially crushed and then treated in order to obtain a canola meal that can be solubilized. As a non-limiting example, Murray discloses the canola meal has a moisture content of about 6.1%, which one of ordinary skill would recognize to be essentially equivalent. Rosseti et al. teach that a meal can be obtained from an oil-extraction technique followed by a desolventizing under vacuum technique in order to obtain essentially a "desolventized oil seed meal. Therefore, it would be reasonable for one of ordinary skill to recognize that the desolventized oil seed meal can be used as the initial canola meal preparation that is processed in the method of Murray for obtaining a protein isolate.

Claims 3-4, 11-16, 20-28, 32-34, 36-43, 51-53 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is (571)272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Maryam Monshipouri/

Primary Examiner, Art Unit 1656

September 25, 2008